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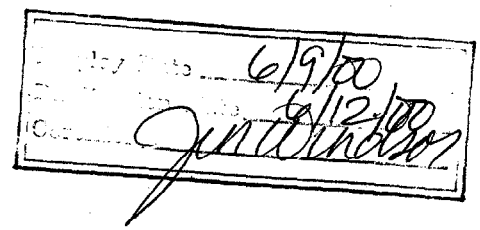

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00M–0811, 00M–1215, 00M–1216, 00M–0915, 99M–4619, 00M–0901, 99M–4763, 00M–0424, 00M–1073, 00M–0577, 00M–0579, 00M–0599, 00M–0445, 00M–0580, 00M–0578, 00M–0810, 00M–0809, 00M–1212]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMA's) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMA's through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Summaries of safety and effectiveness are available on the Internet at http:// www.fda.gov/cdrh/pmapage.html. Copies of summaries of safety and effectiveness are also available by submitting a written request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 in the **SUPPLEMENTARY INFORMATION** section of this document when submitting a written request.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

NAD 1

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's Internet home page at http://www.fda.gov; by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch; and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMA's and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from January 1, 2000, through March 31, 2000. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE JANUARY 1, 2000, THROUGH MARCH 31, 2000

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970005/00M–0811	Kremer Laser Eye Center	Kremer Exciber Laser System (Serial #KEA940202)	July 30, 1998
P970055/00M–1215	Biotrin International, Ltd.	Biotrin Parvovirus IgM EIA (V619IMUS)	August 6, 1999
P970054/00M–1216	Biotrin International, Ltd.	Biotrin Parvovirus IgG EIA (V519IGUS)	August 6, 1999
P980049/00M–0915	ELA Medical, Inc.	Defender II Model 9201 Implantable Cardiovascular Defibrillator	September 15, 1999
H990003/99M–4619	American Medical Systems	Acticon™ Neosphincter	September 20, 1999
P850022(S9)/00M–0901	Biolectron Inc.	SpinalPak® Stimulator	September 24, 1999
H990005/99M–4763	Nitinol Medical Technologies	CardioSEAL® Septal Occlusion System	September 28, 1999
P930034(S12)/00M–0424	Summit Technology	SVS Apex Plus Excimer Laser Workstation w/the Emphasis Discs	October 21, 1999
P910066(S11)/00M–1073	Orthologic Corp.	Orthologic™ 1000 Bone Growth Stimulator	December 17, 1999
P990035/00M–0577	Sunlight Ultrasound Technologies, Ltd.	The Sunlight™ Omnisense Ultrasound Bone Sonometer	January 20, 2000
P990066/00M–0579	GE Medical Systems	Senographe 2000D	January 28, 2000
H990011/00M–0599	Nitinol Medical Technologies	CardioSEAL® Septal Occlusion System	February 1, 2000
P980040/00M–0445	Allergan Inc.	Sensar Soft Acrylic UV–Light Absorbing Posterior Chamber Intraocular Lens	February 3, 2000
P990016/00M–0580	McCue Corporation, Inc.	McCue CUBAClinical Ultraonic Bone Sonometry System w/CUBAplus+V4.1.0	February 15, 2000
P940034(S8)/00M–0578	Gen-Probe Incorporated	Gen-Probe® Amplified™ Mycobacterium Tuberculosis Direct (MTD) Test	February 15, 2000
P900009(S6)/00M–0810	Smith & Nephew Inc.	Exogen 2000 or Sonic Accelerated Fracture Healing System	February 22, 2000
P990023/00M–0809	Alcon Labs	Cellugel® Ophthalmic Viscosurgical Device	February 24, 2000
P950019(S9)/00M–1212	United States Surgical Corp.	Ray Threaded Fusion Cage (TFC) w/ Instrumentation	March 2, 2000

Dated: 5/23/00
May 23, 2000

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Linda S. Kahan
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Center for Devices and Radiological Health

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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